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other employee benefit, arising from employment with a substantially affected organization.

NOTE TO PARAGRAPH (d)(1): NIH employees, as opposed to spouses and minor children of employees, are generally prohibited under $\S5501.109$ from engaging in current employment with a substantially affected organization

- (2) De minimis holdings. A senior employee or spouse or minor child of a senior employee may have a financial interest in a substantially affected organization if:
- (i) The aggregate market value of the combined interests of the senior employee and the senior employee's spouse and minor children in any one substantially affected organization is equal to or less than the *de minimis* exemption limit for matters involving parties established by 5 CFR 2640.202(a) or \$15,000, whichever is greater;
- (ii) The holding, if it represents an equity interest, constitutes less than 1 percent of the total outstanding equity of the organization; and
- (iii) The total holdings in substantially affected organizations and sector mutual funds that, in the literature they distribute to prospective and current investors or participants, state the objective or practice of concentrating their investments in the securities of substantially affected organizations account for less than 50 percent of the total value of the combined investment portfolios of the senior employee and the senior employee's spouse and minor children.
- (3) Diversified mutual funds. A senior employee or spouse or minor child of a senior employee may have an interest in a substantially affected organization that constitutes any interest in a publicly traded or publicly available investment fund (e.g., a mutual fund), or a widely held pension or similar fund, which, in the literature it distributes to prospective and current investors or participants, does not indicate the objective or practice of concentrating its investments in substantially affected organizations, if the employee neither exercises control nor has the ability to exercise control over the financial interests held in the fund.
- (4) Exceptional circumstances. In cases involving exceptional circumstances,

the NIH Director or the NIH Director's designee, with the approval of the designated agency ethics official or his designee, may grant a written exception to permit a senior employee, or the spouse or minor child of a senior employee, or a class of such individuals, to hold a financial interest in a substantially affected organization based upon a determination that the application of the prohibition in paragraph (c) of this section is not necessary to ensure public confidence in the impartiality or objectivity with which HHS programs are administered or to avoid a violation of part 2635 of this title.

- (5) Technology transfer. A senior employee may have a financial interest in connection with the development and commercialization of invention rights obtained by the employee pursuant to Executive Order 10096, 15 U.S.C. 3710d, or implementing regulations.
- (6) Sector mutual funds. (i) A senior employee or spouse or minor child of a senior employee may have an interest in a substantially affected organization that constitutes any interest in a sector mutual fund that, in the literature it distributes to prospective and current investors or participants, does not indicate the objective or practice of concentrating its investments in the biomedical science, pharmaceutical, medical device, biotechnology, or health industry sectors.
- (ii) A senior employee or spouse or minor child of a senior employee may have an interest in a substantially affected organization that constitutes any interest in a sector mutual fund that, in the literature it distributes to prospective and current investors or participants, states the objective or practice of concentrating its investments in the securities of substantially affected organizations provided that:
- (A) The aggregate market value of the combined ownership interests of the senior employee and the senior employee's spouse and minor children in such sector funds is equal to or less than the *de minimis* exemption limit for sector mutual funds established by 5 CFR 2640.201(b)(2)(i) or \$50,000, whichever is greater; and
- (B) The total holdings in substantially affected organizations and in

sector mutual funds that, in the literature they distribute to prospective and current investors or participants, state the objective or practice of concentrating their investments in the securities of substantially affected organizations account for less than 50 percent of the total value of the combined investment portfolios of the senior employee and the senior employee's spouse and minor children.

NOTE TO PARAGRAPH (d): With respect to any excepted financial interest, employees are reminded of their obligations under 5 CFR part 2635, and specifically their obligation under subpart D to disqualify themselves from participating in any particular matter in which they, their spouses or minor children have a financial interest arising from publicly traded securities that exceeds the de minimis thresholds specified in the regulatory exemption at 5 CFR 2640.202 or from non-publicly traded securities that are not covered by the regulatory exemption. Furthermore, the agency may prohibit or restrict an individual employee from acquiring or holding any financial interest or a class of financial interests based on the agency's determination that the interest creates a substantial conflict with the employee's duties. within the meaning of 5 CFR 2635.403.

(e) Reporting and divestiture. For purposes of determining the divestiture period specified in 5 CFR 2635.403(d), as applied to financial interests prohibited under paragraph (c) of this section, the "date divestiture is first directed" means the date on which the new entrant public or confidential financial disclosure report required by part 2634 of this title or any report required by \$5502.107(c) of this chapter is due.

[70 FR 5562, Feb. 3, 2005, as amended at 70 FR 51571, Aug. 31, 2005]

§ 5501.111 Awards tendered to employees of the National Institutes of Health.

- (a) Applicability. This section does not apply to special Government employees.
- (b) *Definitions*. For purposes of this section, official responsibility has the meaning set forth in 18 U.S.C. 202(b).
- (c) Additional limitations on awards to employees of the National Institutes of Health. The following limitations shall apply to the acceptance by an employee of an award pursuant to 5 CFR 2635.204(d):

- (1) Limitations applicable to employees with official responsibility for matters affecting an award donor. An employee shall not accept a gift with an aggregate market value of more than \$200, or that is cash or an investment interest, that is an award or incident to an award from a person, organization, or other donor that:
- (i) Is seeking official action from the employee, any subordinate of the employee, or any agency component or subcomponent under the employee's official responsibility;
- (ii) Does business or seeks to do business with any agency component or subcomponent under the employee's official responsibility;
- (iii) Conducts activities substantially affected by the programs, policies, or operations of any agency component or subcomponent under the employee's official responsibility; or
- (iv) Is an organization a majority of whose members are described in paragraphs (c)(1)(i) through (iii) of this section.
- (2) Prior approval of awards—(i) No employee shall accept an award under 5 CFR 2635.204(d) or this section unless the receipt thereof has been approved in writing in advance in accordance with procedures specified by the designated agency ethics official, or with the concurrence of the designated agency ethics official, the NIH Director or the NIH Director's designee.
- (ii) Approval shall be granted only upon a determination that acceptance of the award is not prohibited by statute or Federal regulation, including 5 CFR part 2635 and this part.

NOTE TO PARAGRAPH (c): In some circumstances cash and other things of value provided in connection with the provision of personal services, including speaking or writing, may be compensation, not a gift. Other ethics rules governing outside activities may restrict receipt of such compensation. See. for example, 5 CFR 2635.807.

(d) Exception. Notwithstanding the prohibition in paragraph (c)(1) of this section, the NIH Director (or the Secretary, with respect to awards tendered to the NIH Director), with the approval of the designated agency ethics official, may grant a written exception to permit an employee to accept an award

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otherwise prohibited by this section under the following conditions:

- (1) There is a determination by the NIH Director (or the Secretary, with respect to awards tendered to the NIH Director) that acceptance of the gift will further an agency interest because it confers an exceptionally high honor in the fields of medicine or scientific research. The following criteria will be considered in making such a determination:
- (i) The identity of the awarding organization:
- (ii) The longevity of the awards program;
- (iii) The source of award funds;
- (iv) The size of the monetary component of the award recognition;
- (v) The identity and credentials of past award recipients;
- (vi) The degree of publicity attendant to receipt of the award; and
- (vii) The impact of the substantive contribution being recognized;
- (2) Absent the prohibition in paragraph (c)(1) of this section, the gift would be permitted under part 2635 of this title; and
- (3) The designated agency ethics official shall have determined that the application of the prohibition in paragraph (c)(1) of this section is not necessary to ensure public confidence in the impartiality or objectivity with which NIH programs are administered or to avoid a violation of part 2635 of this title.
- (e) Disposition of improperly accepted awards—(1) Failure to obtain prior approval. If an employee accepts an award for which approval is required under paragraph (c)(2) of this section without obtaining such approval, the employee may be required, in addition to any penalty provided by law and applicable regulations, to forfeit the award by returning it to the donor.
- (2) Receipt of prohibited award. If an employee accepts an award prohibited by paragraph (c)(1) of this section, the employee shall be required, in addition to any penalty provided by law and applicable regulations, to:
- (i) Reject the award and instruct the donor to strike the honoree's name from any list of award recipients;

- (ii) Remove the recognition from the employee's résumé or curriculum vitae:
- (iii) Return any tangible indicia of the recognition to the donor; and
- (iv) Forfeit the award by returning it to the donor.

[70 FR 5563, Feb. 3, 2005, as amended at 70 FR 51572, Aug. 31, 2005]

§ 5501.112 One-year disqualification of employees of the National Institutes of Health from certain matters involving an award donor.

An employee, other than a special Government employee, of the National Institutes of Health who has, within the last year, accepted an award permitted under 5 CFR 2635.204(d) or \$5501.111 shall not participate in any particular matter involving specific parties in which the donor is or represents a party unless authorized to do so under 5 CFR 2635.502(d).

[70 FR 5564, Feb. 3, 2005]

PART 5502—SUPPLEMENTAL FINAN-CIAL DISCLOSURE REQUIREMENTS FOR EMPLOYEES OF THE DEPART-MENT OF HEALTH AND HUMAN SERVICES

Sec.

5502.101 General.

5502.102 Annual supplemental report of outside employment or activities.

5502.103 Content of annual supplemental reports.

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5502.105 Agency procedures.

5502.106 Supplemental disclosure of prohibited financial interests applicable to employees of the Food and Drug Administration.

5502.107 Supplemental disclosure of financial interests in substantially affected organizations applicable to employees of the National Institutes of Health.

AUTHORITY: 5 U.S.C. 301, 7301; 5 U.S.C. App. (Ethics in Government Act of 1978); E.O. 12674, 54 FR 15159, 3 CFR, 1989 Comp., p. 215, as modified by E.O. 12731, 55 FR 42547, 3 CFR, 1990 Comp., p. 306; 5 CFR 2634.103.

SOURCE: 70 FR 5564, Feb. 3, 2005, unless otherwise noted.

§5502.101 General.

The regulations in this part apply to employees of the Department of Health and Human Services and supplement

the Executive Branch Financial Disclosure Regulations in 5 CFR part 2634. Any regulation in this part made applicable only to the employees of an HHS component designated as a separate agency under \$5501.102(a) of this chapter shall apply to the employees of that component as defined in \$5501.102(b)(1) of this chapter.

§ 5502.102 Annual supplemental report of outside employment or activities.

Any employee, other than a special Government employee, for whom an outside employment or activity has been approved, or who has participated in any outside employment or activity for which prior approval is required, under part 5501 of this chapter shall file on or before February 28 of each year a report concerning all such activities that were approved or undertaken in the previous calendar year. The annual report shall be filed with the employee's supervisor who shall review the form, in consultation with an agency ethics official, and determine whether the employee has complied with applicable laws and regulations and whether approval of any ongoing outside activity should be cancelled because the activity does not meet the standard in 5501.106(d)(5) of this chapter.

 $[70~{\rm FR}~5564,~{\rm Feb.}~3,~2005,~{\rm as~amended~at}~70~{\rm FR}~51573,~{\rm Aug.}~31,~2005]$

§ 5502.103 Content of annual supplemental reports.

The annual supplemental report of outside employment or activities required by §5502.102 shall include the following information:

- (a) The employee's name, contact information, organizational location, occupational title, grade, step, salary, appointment type, and financial disclosure filing status;
- (b) A list of all outside activities for which prior approval is required under part 5501 of this chapter that were approved pursuant to 5 CFR 5501.106(d) or undertaken within the reporting period. The report must identify the person or organization for whom or with which the employee was to perform the activity and the approval date:
- (c) A statement as to whether the anticipated work described in a previously approved outside activity was

actually performed for the person or organization named in the request for approval;

- (d) For each outside activity actually performed, the beginning date of the relationship with the outside entity, the date(s) personal services were provided, the total number of hours spent and leave used on the activity within the reporting period, and the ending date:
- (e) For each outside activity that remains ongoing at the time of filing the report, a statement as to how long the activity is anticipated to continue, the date on which prior approval expires, and whether a request for renewal of approval is anticipated;
- (f) For each outside activity actually performed, the type and amount of any income and/or reimbursements actually received during the reporting period and the date paid:
- (g) For each outside activity actually performed, the type and amount of any income and/or reimbursements earned during or attributable to the reporting period that were not in fact received during the reporting period and remain due:
- (h) A statement as to whether any change has occurred or is anticipated with respect to information supplied in the original outside activity approval request:
- (i) A description of any change in the nature, scope, or subject matter of any approved activity; and
- (j) A description of any change in jobs or in the duties and responsibilities of the employee's position that occurred after the outside activity was approved.

§5502.104 Confidentiality of reports.

Each report filed under this part is confidential and shall not be disclosed to the public, except as provided under §2634.604(b) of this title.

§ 5502.105 Agency procedures.

(a) The designated agency ethics official or, with the concurrence of the designated agency ethics official, each of the separate agency components of HHS listed in §5501.102(a) of this chapter may prescribe forms for the collection of information under this part and establish procedures for the submission